UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,225	08/31/2000	Bharat M. Chowrira	MBHB00-882-C (250.131)	4785

20306 7590 12/17/2002

MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER	
EPPS, JANET L	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 12/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/653,225	Applicant(s) CHOWRIRA ET AL.
	Examiner Janet L Epps-Ford, Ph.D.	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6-9,14-24,29 and 31* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6-9,14,15,29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1–15 and 25-30 drawn to antisense and enzymatic nucleic acid molecules, and further elects SEQ ID NOs: 1832-1841 (enzymatic nucleic acid molecules), and SEQ ID NOs: 4611-4620 (corresponding substrate sequences) in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the pending claims, and the sequences therein, represent a single unified invention, and that a search of both Groups I and II would not place an undue burden on the Examiner, as the method claims are dependent on the claims encompassing enzymatic and antisense nucleic acid molecules. This is not found persuasive because as stated in the prior Official Action, Group I, claims 1-15, and 25-30, drawn to enzymatic and antisense nucleic acid molecules, and cells comprising said nucleic acid molecules, is classifiable in 536/24.5 and 435/325. Additionally, Group II, claims 16-24, drawn to methods of inhibiting telomerase enzyme activity in a cell, and treating a patient having a condition associated with the level of TERT, is classifiable in 514/44. Due to the differences in classification of the claimed subject matter according to Groups I and II, a search is required in each separate classification. Therefore, a *prima facie* case for restriction has been established as per MPEP § 803, which states: "[F]or purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02."

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1, 4-5, 10-13, 25-28 and 30 are cancelled, claims 2-3, 6-9, 14-24, 29, and 31 are currently pending in the instant application.

3. Claims 16-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

4. Claims 2-3, 6-9, 14-15, 29, and 31 are under examination.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-3, 6-9, 14, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al. in view of Joyce et al. (WO 96/17086 A1).

Claim 2 is drawn to an enzymatic nucleic acid molecule which specifically cleaves RNA derived from a TERT gene, wherein said enzymatic nucleic acid molecule is a DNA enzyme.Claim 3 is drawn to an enzymatic nucleic acid molecule of claim 2 wherein said enzymatic nucleic acid molecule comprises any of the DNAzyme sequences as identified as SEQ ID NO: 1832-1841. Claim 31 recites an enzymatic nucleic acid molecule of claim 2 having one or more binding arms comprising a sequence that is complementary to any of the substrate sequences identified as SEQ ID NOs: 4611-4620. Claims 6-9 and 29 recite enzymatic molecules comprising at least one modification, or wherein said enzymatic nucleic acid is chemically

synthesized. Claim 14 recites a mammalian cell including the enzymatic nucleic acid molecule of claim 2.

Yokoyama et al. disclose hammerhead ribozymes that target the 5'-end of the hTERT mRNA and suppress telomerase activity. In one specific embodiment, Yokoyama et al. disclose the ribozyme sequence according to 13RZ, this sequence is designed to recognize the following sequence of hTERT mRNA: 5'-GCAGCGUGCGUCCUGCUCGCCACGU-3' (See Figure 2, page 317). This sequence corresponds to the substrate sequences according to SEQ ID NOS: 4611-4614 as indicated in the specification as filed Table VI. However, Yokoyama et al. does not disclose DNAzymes targeting hTERT mRNA.

Joyce et al. teach the design and synthesis of DNAzymes, Figure 8-9 of Joyce et al. describe the core structure of the 10-23 DNAzyme molecules of the present invention comprising the following sequence: 5'-GGCTAGCTACAACGA-3'. Binding arms that comprise about 14 nucleotides that are complementary to sequences in the substrate to be cleaved flanks this DNAzyme sequence. Moreover all of the DNAzyme molecules according to SEQ ID NO: 1832-1841 of the instant application comprise the same core sequence as the 10-23 DNAzyme, however the DNAzymes of Joyce et al. differ from the DNAzymes of the instant application in that they do not comprise binding arms that are complementary to the substrate sequences according to SEQ ID NOs: 4611-4620 of hTERT mRNA.

Joyce et al. also disclose wherein the enzymatic molecule is chemically synthesized (page 43, line 7); and wherein said enzymatic nucleic acid molecule comprises nucleotide analogs, wherein said nucleotide analog encompasses altered bases, different sugars (for example 2'-O-methylcytidine or 2'-O-methylguanosine), altered phosphate backbones, or any combination

thereof (see page 17, lines 30-37; and page 18, Table 1). Additionally, Joyce et al. contemplates wherein the DNAzymes are used within cells present inside a cell, including plant, animal, yeast and bacterial cells (see page 26, lines 10-14).

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the teachings of Yokoyama et al. with the teachings of Joyce et al. in the design of the enzymatic nucleic acid molecules according to the present invention. One of ordinary skill in the art at the time of filing would have been motivated to modify the enzymatic nucleic acid molecules of Yokoyama et al. which target hTERT mRNA, to comprise a DNAzyme structure according to Joyce et al. which targets hTERT mRNA, because the DNAzymes (i.e. DNA enzymes) offer several important advantages compared to other macromolecular catalysts, including ribozymes as recited in Yokoyama et al. First, they are easy to prepare, in an era when most laboratories have access to an automated DNA synthesizer and the cost of DNA phosphoramidites has become quite modest. Second, they are very stable compounds, especially compared to RNA, thus facilitating their use in biophysical studies. Third, in vitro selection could be carried out with DNA analogues, including compounds that are nuclease resistant such as phosphorothioate-containing DNA. Finally, DNA enzymes offer a new window on our understanding of the macromolecular basis of catalytic function (page 43, lines 5-18).

Furthermore, it would have been obvious to one of ordinary skill in the art to substitute one functionally equivalent nucleic acid catalyst for another since the DNAzymes of Joyce et al. are disclosed as being functionally equivalent to the ribozymes of Yokoyama et al.

Therefore, the invention as a whole is *prima facie* obvious over Yokoyama et al. in view of Joyce et al.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps, Ph.D.
Examiner
Art Unit 1635

JLE

December 16, 2002

SEAN McGARRY
PRIMARY EXAMINER
1635